

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA**

**LISA RENEE DANIELS,
INDIVIDUALLY AND AS THE NEXT
FRIEND OF MINOR A.K.D.
AND ON BEHALF OF ALL OTHERS
SIMILARLY SITUATED,**

JURY TRIAL DEMANDED

Plaintiffs,

CIVIL ACTION NO.: 2:21-cv-00466

v.

**McKINSEY AND COMPANY, INC.
McKINSEY AND COMPANY, INC. UNITED STATES,
McKINSEY AND COMPANY, INC., WASHINGTON, D.C.,**

Defendants.

PERSONAL INJURY COMPLAINT

NOW COME Plaintiffs LISA RENEE DANIELS, as the next friend of MINOR A.K.D hereby filing their Complaint against McKinsey & Company, Inc., McKinsey & Company, Inc. United States and McKinsey & Company, Inc., Washington, D.C. for damages, equitable, statutory, and injunctive relief. In support thereof, Plaintiffs state as follows:

INTRODUCTION

1. Like thousands of children born every year, minor A.K.D. was born dependent on opioids. Prenatal exposure to opioids injured minor A.K.D. causing severe withdrawal symptoms, and lasting developmental impacts.

2. Defendants substantially contributed to minor A.K.D.'s Injuries by masterminding an industry-wide conspiracy aimed at increasing their clients' profits through an illegal scheme that fueled the genesis and continuation of minor A.K.D.'s mother's fatal addiction.

3. The first days of minor A.K.D.'s life was excruciatingly painful and agonizing as

doctors weaned the newborn baby from in utero opioid exposure.

4. Minor A.K.D. will require years of treatment and counseling to deal with the effects of prenatal exposure and its lifelong impact upon A.K.D.'s health, self-esteem, and education and earnings capacity. Minor A.K.D. is a casualty of the opioid crisis that has ravaged West Virginia due to the tortious conspiracy and negligence of McKinsey, and the nuisance caused by its wrongful conduct.

5. Upon information and belief, minor A.K.D.'s birth mother consumed opioids manufactured or distributed by consultancy clients of the Defendant.

6. Defendant McKinsey, a preeminent global business consultancy, dispensed advice to Johnson & Johnson, Purdue, Endo, Amerisource Bergen, among others, that drove the Opioid Crisis of which the Plaintiff is a victim, and whose injuries were proximately caused by the acts and omissions of Defendant McKinsey.

7. Defendant McKinsey provided a wide array of consultancy services to certain manufacturers and distributors working together to alter the standard care for patients experiencing pain which proximately caused injury to the Plaintiff.

8. Defendant McKinsey skillfully crafted communications and developed campaigns for and on behalf of manufacturers and distributors deliberately intended to deflect and diffuse anti-Opioid messages to benefit manufacturers and distributors, alike, in terms of enhanced sales and increased profits. McKinsey is also responsible for exacerbating and fueling both the diversionary-opioid and prescription-opioid markets, and for proximately causing injury to the Plaintiff by reason of the fact that Plaintiff's birth mother became addicted to the products manufactured by McKinsey client Endo and prescribed to her during a time period following dissemination of aforementioned McKinsey-created materials.

9. Similarly, McKinsey is responsible and liable for causing injury to the Plaintiff because the Plaintiffs' birth mother, during the first trimester of pregnancy was using opioid products purchased from the diversionary market that was both exacerbated and fueled by the McKinsey's work product.

10. Defendant McKinsey developed and implemented sales strategies that proximately caused the Plaintiffs' injuries because the doctor who prescribed the minor A.K.D's birth mother the Percocet that began her addiction was targeted by the marketing strategies to be amenable to be persuaded into prescribing the more potent, more profitable, and more addictive products offered by the Defendants' clients.

11. Defendant McKinsey developed and implemented sales strategies that proximately caused the Plaintiffs' injuries because the Plaintiff's birth mother consumed opioids from the diversionary market that supplied from the high decile doctors targeted by the sales strategies developed by McKinsey.

12. Defendant McKinsey developed and implemented a marketing strategy that drove the diversionary market which proximately caused the Plaintiffs' injuries by supplying an illegal market that continued to fuel the birth mothers' addiction even after gestation began.

13. Defendant McKinsey misled the federal government in its report regarding the Opioid Crisis by identifying completely ignoring the prevalence of NAS and instead directing blame to mothers of NAS victims.

14. Defendant participated in a conspiracy to violate federal and state laws regulating the distribution of opioids.

15. Defendants thus intentionally and negligently created conditions in which vast amounts of opioids have flowed freely from drug manufacturers to innocent patients who became

addicted, to opioid abusers, and even to illicit drug dealers - with distributors regularly fulfilling suspicious orders from pharmacies and clinics, who were economically incentivized to ignore “red flags” at the point of sale and before dispensing the pills.

16. Defendants’ wrongful conduct has allowed billions of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in West Virginia which in turn contributed to the diversionary market throughout the U.S. This is characterized as “opioid diversion.” Acting against their common law and statutory duties, Defendants have created an environment in which opioid diversion is rampant. As a result, unknowing patients and unauthorized opioid users have ready access to illicit sources of diverted opioids.

17. For years, Defendants and their agents have had the ability to substantially reduce the consequences of opioid diversion, including the dramatic increase in the number of infants born with NAS. All the Defendants in this action share responsibility for perpetuating the epidemic and the exponential increase in the number of infants afflicted with NAS.

18. Defendants have foreseeably caused damages to minor A.K.D. including the costs of neo-natal medical care, additional therapeutic, prescription drug purchases and other treatments for NAS afflicted newborns, and counseling and rehabilitation services after birth and into the future. Plaintiffs bring this civil action for injunctive relief, compensatory damages, statutory damages, and any other relief allowed by law against the Defendant opioid drug distributors, retailers, and manufacturers that, by their actions and omissions, knowingly or negligently have distributed and dispensed prescription opioid drugs in a manner that foreseeably injured and continues to injure minor A.K.D..

PARTIES

A. Plaintiffs

19. Plaintiff Lisa Renee Daniels is a resident of Charleston, WV. Plaintiff is the grandmother and next friend of minor A.K.D.

20. Minor A.K.D.'s birth mother was prescribed opioid drugs during pregnancy, which lead to NAS Symptoms in minor A.K.D. Minor A.K.D.'s birth mother's prescription history includes Acetaminophen with Codeine (prescribed in December 2005) Hydromorphone (first prescribed May 2008, and again in October 2008 and May 2010), Naltrexone (prescribed in May 2010). Buprenorphine/Naloxone (prescribed in June 2019), and Suboxone (prescribed April-May 2019, the time of A.K.D.'s birth). Plaintiff received her prescriptions from Fruth Pharmacy in Huntington, WV and Marshall Pharmacy in Huntington, WV. Plaintiff's birth mother is deceased. Minor A.K.D. was born September, 18 2019 and suffered NAS at birth. Minor A.K.D. was born several weeks premature by emergency C-Section due to low amniotic fluid. Minor A.K.D. was diagnosed with NAS at birth and suffered from symptoms including tremors and convulsions, diarrhea, signs of excessive sucking, excessively runny nose, high pitched screaming, and irritability. Minor A.K.D. now suffers from respiratory issues, irritable bowel problems, chronic diarrhea and gastrointestinal problems, growth and developmental delays, and social and behavioral difficulties.

21. Minor A.K.D. is an individual who has suffered Neonatal Abstinence Syndrome as a result of exposure to opioids in utero. This drug exposure provides minor A.K.D. the right to sue, through her next friend and guardian, for damages under product liability, express warranty, implied warranty of fitness for a particular purpose, implied warranty of merchantability, nuisance, negligence, and gross negligence.

22. Minor A.K.D. directly and foreseeably sustained all damages alleged herein. Categories of past and continuing sustained damages include, inter alia: (1) costs for providing treatment of infants born with opioid-related medical conditions like NAS; (2) equitable relief of medical monitoring, testing and treatment for latent dread diseases associated with NAS (3) costs for providing ongoing medical monitoring care into a Court administered fund, additional therapeutic and prescription drug purchases, and other treatments; (4) costs for providing treatment, counseling and rehabilitation services; and (5) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation, including foster care services.

23. Minor A.K.D. has suffered and continue to suffer these damages directly. Plaintiffs also seek the means to abate the epidemic Defendants' wrongful and/or unlawful conduct has created.

DEFENDANT

24. Upon information and belief, McKinsey & Company, Inc. ("McKinsey & Co.") maintains a principal place of business in New York, New York, and it is incorporated under the laws of the State of Delaware. During all relevant times, McKinsey & Co. has provided consultancy services to manufacturers and distributors of a wide variety of opioid products, all of whom are complicit and responsible for the shipment of substantial amounts of prescription opioids into West Virginia.

25. Upon information and belief, McKinsey & Company, Inc.- United States ("McKinsey-US") maintains principal place of business in New York, New York, and it is incorporated under the laws of the State of Delaware. During all relevant times, McKinsey-US has provided consultancy services to manufacturers and distributors, all of whom are complicit

and responsible for the shipment of substantial amounts of prescription opioids into West Virginia.

26. McKinsey & Company, Inc.- District of Columbia (“McKinsey-DC”) maintains a principal place of business in New York, New York, and it is incorporated under the laws of the State of Delaware. During all relevant times, McKinsey-DC has provided consultancy services to manufacturers and distributors, all of whom are complicit and responsible for the shipment of substantial amounts of prescription opioids into West Virginia.

27. Defendants McKinsey & Co, McKinsey- US and McKinsey-DC will be collectively referred as “McKinsey.”

CO-CONSPIRATORS

28. Co-Conspirator AmerisourceBergen Corporation, upon information and belief, maintains a principal place of business in Pennsylvania, and it is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen has assiduously sought, implemented and compensated McKinsey in connection with its provision of consultancy services leading to the shipment of substantial amounts of prescription opioids to providers and retailers situated in the State of West Virginia.

29. Co-Conspirator Cephalon, Inc. (“Cephalon”), upon information and belief, maintains a principal place of business in Frazer, Pennsylvania, and it is organized under the laws of the State of Delaware. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and West Virginia. Actiq and Fentora have been approved by the FDA only for the “management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.” In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay \$425

million. Cephalon, Inc. has assiduously sought, implemented, and compensated McKinsey in connection with its provision of consultancy services leading to substantial amounts of prescription opioids to providers and retailers in the State of West Virginia.

30. Co-Conspirator Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”) is, upon information and belief, an Israeli corporation with its principal place of business in Petah Tikva, Israel. Related entity Teva Pharmaceuticals USA, Inc. (“Teva USA”) is, upon information and belief, a wholly-owned subsidiary of Teva Ltd., and it is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Teva derived direct and indirect pecuniary benefit from McKinsey’s professional advice and consultancy services that Cephalon sought, implemented and paid for; the objective was to make more money from the inordinate —unconscionable-- amounts of prescription opioids being distributed to providers and retailers operating within the State of West Virginia.

31. Together, co-Conspirators Teva Ltd., Teva USA, Cephalon, and McKinsey collaborated and colluded to market and sell Cephalon products in the United States.

32. Teva Ltd. is the entity responsible for all of Cephalon’s sales and marketing activities within the United States, through related entity Teva USA. Teva Ltd. and Teva USA publicize and promote Actiq and Fentora as being Teva products. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide (the Guide”), which is distributed with Cephalon opioids marketed and sold in West Virginia, discloses that the Guide was submitted by Teva USA, and it explicitly directs physicians to contact Teva USA to report adverse events.

33. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed throughout West Virginia, certifying that Teva

Ltd. would be responsible for covering certain described co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo.

34. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own; all financials are consolidated. Through interrelated corporate structures, Teva Ltd. operates in West Virginia and the rest of the United States. through its two subsidiaries Cephalon and Teva USA. The United States. is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015; significantly, were it not for the existence of subsidiaries Teva USA and Cephalon, Inc., Teva Ltd. would be constrained to conduct its business operations from West Virginia only. Upon information and belief, Teva Ltd. directs and controls the business practices of Cephalon and Teva USA, and the profits of these two subsidiaries directly and exclusively inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. Are sometimes hereinafter collectively referred to as "Cephalon.")

35. Co-Conspirator Janssen Pharmaceuticals, Inc. ("Janssen"), upon information and belief, a Pennsylvania corporation that maintains a principal place of business in Titusville, New Jersey.

36. Janssen is a wholly owned subsidiary of Johnson & Johnson ("J&J").

37. J&J is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

38. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen, is a Pennsylvania corporation with its principal place of business, like Janssen, located in Titusville, New Jersey.

39. J&J is the only company that owns more than 10% of Janssen's stock, and J&J (not

Janssen) corresponds with the FDA regarding Janssen's products.

40. Upon information and belief, J&J controls the sale and development of Janssen's drugs and Janssen's profits inure directly and exclusively to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are sometimes collectively referred to as "Janssen.").

41. Janssen manufactures, promotes, sells, and distributes drugs including but not limited to the opioid Duragesic, in the United States, including West Virginia. Before 2009, Duragesic accounted for at least \$1 billion in annual sales.

42. Until January 2015, Janssen developed, marketed, and sold opioids under the names Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

43. Co-Conspirator Endo Health Solutions Inc. ("Endo Health") is, upon information and belief, a Delaware corporation that maintains a principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. ("Endo Pharma") is, upon information and belief, a Delaware corporation that maintains a principal place of business in Malvern, Pennsylvania, and Endo Pharma is a wholly-owned subsidiary of Endo Health, and (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are sometimes collectively referred to as "Endo.").

44. Endo develops, markets, and sells prescription drugs, including the opioids under the names Opana/Opana ER, Percodan, Percocet, and Zydane, in the United States, including West Virginia. Opioids account for nearly \$403 million of Endo's overall revenues of \$3 billion in 2012. Opana ER accounted for \$1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012.

45. Endo also manufactures and sells generic opioids such as oxycodone,

oxymorphone, hydromorphone, and hydrocodone products throughout the United States, including West Virginia, either by itself or through its subsidiary, Qualitest Pharmaceuticals, Inc.

46. Co-Conspirator J&J either was at relevant times or currently owner and operator of wholly owned subsidiaries Janssen, Noramco, Inc. and Tasmanian Alkaloids,

47. J&J sought out, implemented, and paid for McKinsey's the professional advice and consultancy services, for purposes of making more money and profits from the shipment of opioids to West Virginia, in addition to cultivating and exploiting and, thereby, monetizing J&J's world-wide narcotics franchise. J&J is liable for conspiring with McKinsey, Purdue, Endo, Cephalon and Amerisource Bergen.

48. Cephalon, Janssen, Endo, J&J, Teva and McKinsey are collectively referred to hereinafter as the "Co-Conspirators".

JURISDICTION AND VENUE

49. Jurisdiction of this Court arises under 28 U.S.C. § 1332(a) as the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of attorney's fees and costs.

50. Minimal diversity exists between named Plaintiffs of this action, citizens of the State of West Virginia, and Defendants. Further, the amount in controversy exceeds \$5,000,000.00.

51. Defendants have, alone and in combination, systematically, individually, jointly, and severally engaged in conduct and activities over a period of years in West Virginia and are the proximate cause of all of the damages sustained by Plaintiffs, minor A.K.D. all of which form the bases of the causes of action in this Complaint as against Defendants. Defendants have committed multiple torts and breaches within the State of West Virginia, repeatedly and

systematically.

52. Defendants, for a long time, repeatedly and systematically, have substantial contacts and business relationships within West Virginia and its patients and citizens, including consensual relationships and contracts performed within West Virginia, some or all of which form the basis of the causes of action in this Complaint as against Defendants.

53. This Court has personal jurisdiction over Defendants, each of which has committed torts, in part or in whole, within the State of West Virginia, as alleged herein. Moreover, Defendants have substantial contacts and business dealings directly within West Virginia by virtue of their actions and commissions in connection with distribution, dispensing, and marketing and sales, of prescription opioids. All causes of action herein relate to Defendants' wrongful actions, conduct, commissions, and omissions committed against Plaintiffs, minor A.K.D. and the consequences and damages related to said wrongful actions, conduct, and omissions.

54. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events giving rise to the claims occurred in the Southern District of West Virginia.

FACTUAL ALLEGATIONS OF DEFENDANTS' CONSPIRATORIAL CONDUCT

55. Beginning in the mid-1990s, opioid manufacturers pursued aggressive sales strategies to increase sales of their prescription opioids, a plan that resulted in a dramatic rise in opioid prescriptions in West Virginia. The rise in opioid prescriptions caused an equally devastating rise in opioid use disorder, dependence, addiction, and overdose deaths; as well as a dramatic increase in instances of Neonatal Abstinence Syndrome ("NAS"), in which children born to opioid addicted mothers suffer both acute and long-lasting physical, psychological, and developmental injury.

56. Children born with NAS suffer the effects of the opioid epidemic from the moment

of birth, experiencing acute withdrawals and a higher risk of birth defects immediately. As these children with NAS age, they will experience significant behavioral, developmental, and psychological symptoms on their way to adulthood. These children will require long-term care.

57. Prescription opioids continue to kill hundreds of people across West Virginia every year. Thousands more suffer from negative health consequences short of death and countless others have had their lives ruined by a friend or family member's addiction or death. Every community in West Virginia suffers from the opioid crisis of addiction and death. Thousands more babies are born with NAS in West Virginia every year as the Opioid Crisis continue unabated. Every community in West Virginia carries the burden of caring for, educating, and raising the vast number of children born with NAS in the state each year.

58. West Virginia has one of the highest incidences of NAS Births in the nation. According to statistics from the West Virginia Department of Health and Human Resources ("WVDHHR"), West Virginia recorded 50.6 NAS births per 1,000 babies born in the state in 2016-2018 alone. Intrauterine drug exposure rates, the underlying cause of NAS, are even higher in West Virginia, recorded at 143 instances per 1,000 births according to WVDHHR statistics.

59. These alarming numbers of NAS births in West Virginia could not have been possible without McKinsey's advice to Purdue and co-conspirators. According to the DEA ARCOS database ("ARCOS Data"), which tracks shipments of all opioid drugs from labelers and distributors to pharmacies on a national basis, between 2006 and 2012, the number of opioid drugs in West Virginia surged to unprecedented levels as McKinsey's advice was put into practice first by Purdue, and later co-conspirators. According to this data, the number of Purdue opioids shipped to West Virginia during these years amounted to 952,781,390 milligrams of morphine equivalent ("MME"), or 16,919,660 individual pills or "total dosage units" ("TDU"). When divided by

population, this equals to 515mg of morphine equivalent for each man, woman, and child in West Virginia.

60. As McKinsey emulated Purdue's success in advice to Co-Conspirators, these companies similarly experienced wild profits in West Virginia as prescriptions and demand for their opioid drugs increased. According to ARCOS data, between 2006 and 2012, co-conspirators sent shockingly large amounts of powerful opioid drugs to pharmacies in West Virginia. During this time frame Janssen Pharmaceuticals shipped 328,373,951 MME or TDU; Endo shipped 229,710,534 MME or 8,453,120 TDU; Teva shipped 196,953,618 MME or 11,679,117 TDU; and Cephalon shipped 662,272 MME or 8,776 TDU to pharmacies, and ultimately, the citizens of West Virginia. The proliferation of opioids around the state and the profits of McKinsey and co-conspirators correlates directly with the increase in children born in West Virginia with NAS.

61. McKinsey diligently advised entities involved with the manufacturing and sale of opioids on how to maximize profits by generating the maximum number of prescriptions for opioid drugs, thereby contributing to the opioid crisis and high rates of children born with NAS in West Virginia.

62. McKinsey is one of the world's largest consulting companies. Its partners work worldwide for corporations and governments across diverse industries. Its influence is vast because of its "best-in-class" reputation. McKinsey sells the notion that it can take whatever a company or government is doing and make them do it better.

63. Plaintiff brings this action against McKinsey for the consulting services it provided to opioid companies in connection with designing the companies' marketing plans and programs that helped cause and contribute to the opioid crisis. McKinsey sold its ideas to OxyContin maker Purdue Pharma, L.P. ("Purdue") for more than fifteen years, from 2004 to 2019, including before

and after Purdue's 2007 guilty plea for felony misbranding.

64. McKinsey advised Purdue and other manufacturers to target prescribers who write the most prescriptions, for the most patients, and thereby make the most money for McKinsey's clients.

MCKINSEY'S ADVICE SPURS OPIOID PRESCRIPTION DEMAND

65. McKinsey's advice to co-conspirators allowed the opioid crisis to worsen to its current level. McKinsey advised co-conspirators to do whatever it took to proliferate opioid prescriptions in order to maximize their profits, regardless of the cost to the public. Notably, McKinsey's strategy of targeting the highest prescribing physicians proved so successful that sales of Purdue's opioid drugs surged, as did demand for opioid drugs in general. McKinsey replicated this strategy in advice to the co-conspirators, who similarly experienced an uptick in sales. With this, West Virginia saw an even larger surge in opioid addiction, overdose deaths, and instances of children born with NAS.

66. Upon information and belief, McKinsey developed rules for sales staff governing contact and frequency of sales visits to these targeted physicians, as well as goals for prescription volume were set forth. The sales teams were encouraged to place multiple calls per month to the highest decile providers in their territories in attempts to increase the number of opioid scripts written, and sales staff were incentivized by bonuses which correlated directly with these numbers.

67. Beginning as early as 2004, and continuing for over a decade, McKinsey advised Purdue and other pharmaceutical companies (including Johnson & Johnson, Endo, and Cephalon) on how to increase prescriptions and sales of their opioid drugs.

68. McKinsey's initial advice revolved around competitors working together in leveraging the promotion of changes in the standard of care to drive demand for the Opioid Industry as a whole. That advice clearly was a success.

69. Early in their relationship, McKinsey advised Purdue that it could increase OxyContin sales through physician targeting and specific messaging to prescribers. These McKinsey strategies formed the pillars of Purdue's sales tactics for the next fifteen years.

70. In 2008, McKinsey worked with Purdue to develop its FDA mandated risk evaluation and mitigation strategy ("REMS"). McKinsey advised Purdue to "band together" with other opioid manufacturers toward a class REMS to "formulate arguments to defend against strict treatment by the FDA." Ultimately, the FDA adopted a class-wide REMS that resulted in high-dose OxyContin remaining subject to the same oversight as lower-dose opioids.

71. In 2009, Purdue hired McKinsey to increase "brand loyalty" to OxyContin. McKinsey recommended the best ways to ensure loyalty to the brand by targeting specific patients, including patients new to opioids, and developing targeted messaging for specific prescribers.

72. Purdue thereafter adopted McKinsey's proposed prescriber messaging and patient targeting advice and incorporated them into Purdue's marketing and sales strategies.

73. In 2013, McKinsey conducted another analysis of OxyContin growth opportunities for Purdue and laid out new plans to increase sales of OxyContin. Among the key components of McKinsey's plan adopted by Purdue were to:

- i. focus sales calls on high-volume opioid prescribers, including those who wrote as many as 25 times as many OxyContin scripts as their lower volume counterparts;
- ii. Remove sales representative discretion in targeting prescribers;

- iii. Focus Purdue's marketing message to titrate to higher, more lucrative dosages;
- iv. Significantly increase the number of sales visits to high volume prescribers; and
- v. create an "alternative model for how patients receive Oxycontin" including direct distribution to patients and pharmacies, to help address the "product access" problem.

74. Purdue approved McKinsey's plan, and together with McKinsey, moved to implement the plan to "Turbocharg[e] Purdue's Sales Engine," under the name Evolve 2 Excellence ("E2E"). E2E significantly increased Purdue's opioid sales, in particular, for OxyContin.

75. McKinsey partners participated as part of an Executive Oversight Team and Project Management Office, reporting to Purdue's Executive Committee, the Purdue board, and with the Sacklers, individually. McKinsey worked side by side with Purdue and helped Purdue plan and implement E2E, assisting with sales representative training, productivity, messaging, and call plans, IT systems, promotional strategies, and market forecasting.

76. In developing the targeted messaging to increase sales of OxyContin, McKinsey conducted significant market research, including through ride-alongs with Purdue sales representatives to learn how they promoted OxyContin. McKinsey carefully monitored Purdue sales representatives and provided guidance on prescriber messaging and adhering to target prescriber lists. McKinsey advised that sales representatives do more to promote the so-called abuse deterrent properties of a reformulated version of OxyContin to address prescriber concerns about abuse risk.

77. When a large pharmacy chain took steps to scrutinize suspicious opioid orders, McKinsey stressed to Purdue's owners the "need to take action" on this "urgent" issue affecting OxyContin. McKinsey told Purdue's owners to engage in senior level discussions with the pharmacy chain, increase efforts with patient advocacy groups to clamor against dispensing limits, and accelerate considerations of an alternative distribution channel, such as delivering OxyContin directly to patients through mail-order pharmacies.

78. After E2E, McKinsey continued to work with Purdue, including on a project that identified the growing addiction crisis as a profit-making opportunity. McKinsey told Purdue that it should strive to become a provider across the spectrum of drug abuse and addiction because of the opportunities it presented. McKinsey advised Purdue to get into the manufacturing and marketing of opioid rescue and treatment medications in order to profit from the realities of dependence, addiction, and misuse. Indeed, in 2018, Purdue owner Dr. Richard Sackler received a patent for a drug to treat opioid addiction.

79. McKinsey also partnered with Purdue to test a program called FieldGuide, a proprietary software that McKinsey sought to license to other manufacturers. This software would enable other opioid manufacturers to target and aggressively pursue high-volume prescribers.

80. McKinsey continued to design and develop ways that Purdue could increase sales of OxyContin. One proposal McKinsey recommended was for Purdue pay "additional rebates on any new OxyContin related overdose or opioid use disorder diagnosis." McKinsey advised Purdue on its strategies to obtain and maintain broad formulary coverage for OxyContin with insurers and pharmacy benefit managers, even as payors began reducing coverage for OxyContin as the opioid crisis mounted.

81. Subsequently, in the wake of hundreds of thousands of opioid deaths and thousands

of lawsuits, McKinsey proposed a plan for Purdue's exit from the opioid business whereby Purdue would continue selling opioids as a way to fund new Purdue ventures. According to McKinsey, this change was necessary because of the negative events that materially compromised the Purdue brand.

82. McKinsey's work for opioid manufacturers extended beyond Purdue. McKinsey designed and implemented marketing programs for the country's largest opioid manufacturers and distributors, including Johnson and Johnson, Cephalon, and Endo collecting millions of dollars in fees and further increasing the sale and use of opioids, and thereby instances of children born suffering from NAS, in West Virginia.

83. At the same time McKinsey was working for opioid companies, McKinsey also consulted with governments and non-profits working to abate the raging opioid crisis—a crisis that McKinsey's own research showed was caused in large part by prescription opioids.

84. There are indications that individuals at McKinsey considered destroying or deleting documents related to their work for Purdue.

85. In 2019, McKinsey announced that it no longer worked for Purdue or other opioid manufacturers. But the harm created by McKinsey's marketing plans for opioid manufacturers has not stopped.

86. Months after McKinsey stopped its opioid work, Purdue filed for bankruptcy. More than a hundred thousand individuals filed claims for personal injuries. States and local governments filed claims for trillions of dollars incurred as a result of the opioid crisis. Another McKinsey client, opioid manufacturer Mallinckrodt plc, similarly filed for bankruptcy protection in October 2020.

87. In 2019, an Oklahoma state court found that McKinsey client Johnson & Johnson

helped cause the opioid epidemic in Oklahoma, ordering it to pay \$465 million to help abate the crisis.

88. In 2020, Purdue pleaded guilty to three felonies as a result of conduct spanning a decade – from 2007 to 2017 – during which Purdue worked side-by-side with McKinsey to design and implement marketing campaigns to increase dangerous opioid sales.

89. In 2020, Purdue and the members of the Sackler family who owned Purdue also settled civil claims by the Department of Justice for hundreds of millions of dollars. The materials filed in connection with that plea and settlement agreements contain a statement of facts regarding McKinsey's conduct and involvement in the conduct leading to the civil claims against Purdue and the Sackler family.

McKINSEY'S ADVICE DRIVES OPIOID DIVERSION SUPPLY

90. By the time McKinsey was working with Purdue on sales and marketing in 2009, it already had extensive experience with opioids in particular. As early as 2002, McKinsey was advising other opioid manufacturers regarding methods to boost sales of their drugs.

91. Upon information and belief, McKinsey prepared a confidential report for Johnson & Johnson regarding how to market their novel opioid product, the Duragesic fentanyl patch. Incredibly, one of the recommendations McKinsey provided to Johnson & Johnson was that they concentrate their sales and marketing efforts on doctors that were already prescribing large amounts of Purdue's OxyContin.

92. As early as 2002 McKinsey had such intricate knowledge of the sales and marketing practices of opioid manufacturers, generally, and Purdue's efforts with OxyContin, specifically, that it was able to recommend to Purdue's competitors in the opioid market that they boost their own opioid sales by following in the footsteps of Purdue.

93. McKinsey was aware that their advice to the pharmaceutical industry was contributing to opioid abuse and diversion. In 2013, McKinsey briefed Purdue on the ongoing concerns of oxycontin addiction and diversion among prescribers, advising Purdue's marketing and sales teams on how to tailor their messaging to doctors who were growing increasingly wary of prescribing such drugs.

94. Despite this awareness, McKinsey's mandate was to increase opioid sales during a time when Purdue was obligated to restrict its previous marketing strategies because those strategies had caused the overprescribing of opioids and the inevitable consequences thereof. McKinsey's job was to devise strategies to sell as many pills as conceivably possible. Under McKinsey's tutelage, Purdue's growth and the growth of other opioid manufacturers continued its upward trajectory unabated, as national overdose deaths and NAS Births also increased.

95. Perhaps the key insight McKinsey provided to opioid manufacturers was, using its granular approach, to identify historically large prescribers and target ever more sales and marketing resources on them. After seeing much success with this technique in their consulting for Purdue, McKinsey similarly advised opioid manufacturers Johnson & Johnson and Endo to target high prescribing doctors with sales teams to increase opioid prescriptions, as well as prescriptions of higher dosages and more potent dosages.

96. On January 20, 2010, Purdue's board was informed of the ongoing work McKinsey was performing concerning a new "physician segmentation" initiative whereby McKinsey would analyze the opioid prescribing patterns of individual physicians to identify those that had historically been the highest prescribers. McKinsey then worked with Purdue's sales and marketing staff to specifically target those high prescribing doctors with a marketing blitz to encourage even further prescribing of their Opioid drugs. Purdue trained its sales force in tactics

to market to these high prescribers based on McKinsey's insights and designed in conjunction with McKinsey.

97. By all accounts, McKinsey's strategy of physician targeting was a success, and the same techniques honed through their work with Purdue were given to Purdue's competitors. Opioid prescriptions in West Virginia increased exponentially in this period. McKinsey's advice to Purdue, J&J, Endo, and Cephalon to target top-decile contributors drove not only demand for prescriptions but also supply into the diversionary market.

98. In West Virginia, the number of prescriptions written and the number of opioid drugs dispensed during this time period is staggering: according to the DEA ARCOS prescription drug tracking database ("ARCOS Database") between 2008 and 2018, 2.6 million opioid pills were dispensed from the Tug Valley Pharmacy in Williamson, WV (Population 2800 individuals), and 3.7 million hydrocodone pills were dispensed from a pharmacy in the tiny town of Kermit, WV, with a population of only 400 individuals, during this same time period. Westside Pharmacy in Oceana, WV (Pop. 1,394), where Plaintiff filled her prescriptions, sold 7,939,772 opioid pills between 2006 and 2014, according to DEA tracking data.

99. The number of opioids in West Virginia during this time period is so vastly more than small communities such as Oceana could even consume for medical purposes, that it is all but guaranteed many of these pills entered the diversionary market, further increasing the severity of the opioid epidemic and the number of instances of NAS in West Virginia. This would not have been possible without McKinsey's advice to the pharmaceutical industry on how to sell the maximum number of opioids possible.

McKINSEY'S ADVICE PROTECTS DISTRIBUTORS WHO PLED GUILTY

100. McKinsey's advice to AmeriSourceBergen to re-direct criticism onto the addict population allowed AmeriSourceBergen to continue to distribute substantial amounts of pain pills in to West Virginia.

McKINSEY MISLEADS THE FEDERAL GOVERNMENT ABOUT THE IMPACT OF OPIOID DRUGS ON CHILDREN

101. McKinsey misled the federal government as to the impact of the Opioid Crisis on children by only presenting the talking points McKinsey created for its co-conspirators, which sought to redirect blame for the Opioid Crisis onto patients that abuse the drug.

102. McKinsey, with its extensive research capacity, must have known of the extent of the NAS epidemic and therefore must have decided to exclude any mention of hundreds of thousands of children directly harmed by its clients' products.

103. Below are relevant facts of which McKinsey was most certainly aware that should have garnered attention in McKinsey's report:

- a. The incidence of NAS has been increasing in the United States. The Substance Abuse Mental Health Services Administration reported that 1.1% of pregnant women abused opioids (0.9% used opioid pain relievers and 0.2% used heroin) in 2011.¹
- b. In recent years, there has been a dramatic rise in the proportion of infants who have been exposed to opioids. Opioid use among women who gave birth increased in the United States from 1.19 to 5.63 per 1,000 hospital births per year between 2000 and 2009. Concurrently the incidence of neonatal abstinence syndrome (NAS) among newborns during the same period (from 1.20 per 1,000 hospital births per year in 2000 to 3.39 per 1,000 hospital births per year in 2009).²
- c. In a study from Florida, the number of newborns who had NAS and were admitted to the NICU increased by 10-fold from 2005 to 2011, a relevant period when Defendant McKinsey tortiously and negligently conspired with others to drive supply to the diversionary market. Increases in the incidence of NAS have been reported

¹ Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) *Pediatrics* 547, 547-48 (2014), available at <http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf>.

² Patrick, S. W., Schumacher, R. E., Benneyworth, B. D., Krans, E. E., McAllister, J. M., & Davis, M. M. (2012). Neonatal abstinence syndrome and associated health care expenditures: West Virginias, 2000–2009. *Journal of the American Medical Association*, 307(18), 1934–1940.

- uniformly across community hospitals, teaching hospitals, and children's hospital.³
- d. The incidence of NAS in newborns born to opioid-dependent women is between 70 and 95 percent. Research suggests that newborns with NAS (most commonly associated with opioid misuse during pregnancy) are more likely than all other hospital births to have low birthweight or respiratory complications. Untreated heroin and other opioid misuse during pregnancy also is associated with increased risk of placental abruption, preterm labor, maternal obstetric complications, and fetal death.⁴

104. The NAS epidemic and its consequences could have been, and should have been, prevented by the Defendants who control the U.S. drug distribution industry and the Defendants who manufacture the prescription opioids. These Defendants have profited greatly by allowing West Virginia to become flooded with prescription opioids.

105. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders by downstream pharmacies, doctors, clinics, or patients. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

CAUSES OF ACTION

COUNT I - CIVIL CONSPIRACY

106. Plaintiffs reassert the allegations in the foregoing paragraphs as if fully set out herein.

107. Defendants conspired with the Co-Conspirators by taking steps to advise, inform and enable them to engage in tortious activity that proximately caused the injuries alleged herein.

³ Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) *Pediatrics* 547, 547-48 (2014), available at <http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf>.

⁴ Winklbaur, B., Kopf, N., Ebner, N., Jung, E., Thau, K., & Fischer, G. (2008). Treating pregnant women dependent on opioids is not the same as treating pregnancy and opioid dependence. *Addiction*, 103(9), 1429–1440; *see also* American College of Obstetricians and Gynecologists. (2012; reaffirmed in 2014). Opioid abuse, dependence, and addiction in pregnancy (Committee Opinion No. 524). Retrieved from <http://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co524.pdf?dmc=1&ts=20150928T1302076021>; *see also* Kaltenbach, K., Berghella, V., & Finnegan, L. (1998). Opioid dependence during pregnancy: Effects and management. *Obstetrics Gynecology Clinics of North America*, 25(1), 139–151.

108. By garnering information from each Co-Conspirator, the Defendants placed themselves in a position by which Defendants' knowledge of each Co-Conspirators' trade secrets and market performance allowed the Co-Conspirators to act in concert to tortiously and illegally change the standard of care for opioids, drive an oversupply in the prescription market to meet the demands of the diversionary market, deflect criticism/enforcement actions against the co-conspirators and mislead the federal government about nature of the harm to children caused by the Opioid Crisis.

109. No Defendant or co-conspirator in this opioid network would have succeeded in profiting so significantly from the opioid epidemic without the concerted conduct of the other party, and none would have succeeded so significantly without engaging in the wrongful conduct as herein alleged.

110. Each Defendant and co-conspirator likewise benefitted from this conspiracy in that the more pervasive opioid diversion became, the more Defendant and Co-Conspirators profited.

111. As a result of the concerted actions between and among the Defendants, the Plaintiffs have suffered damages.

112. Defendants are jointly and severally liable for the damages inflicted by themselves and all Co-Conspirators.

113. Plaintiff and minor A.K.D. demand judgment against each Defendant for compensatory damages.

COUNT II - NUISANCE

114. Plaintiffs reassert the allegations of the foregoing paragraphs as if set forth fully herein.

115. The nuisance is the over-saturation of opioids in West Virginia for non-medical

purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use, including the increasing incidence of NAS.

116. All Defendants substantially participated in nuisance-causing activities.

117. Defendants' nuisance-causing activities include facilitating the excessive sale of prescription opioids to the patients and citizens of West Virginia, as well as to unintended users, including newborns and children, people at risk of overdose, and criminals.

118. Defendants' nuisance-causing activities also include failing to implement effective controls and procedures in their supply chains to guard against theft, diversion and misuse of controlled substances, and their failure to adequately design and operate a system to detect, halt and report suspicious orders of controlled substances.

119. Defendants' activities unreasonably interfere with the rights of Plaintiffs.

120. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

- a. Has harmed and will continue to harm the children and public health services of West Virginia;
- b. Is proscribed by statutes and regulation, including the CSA and the consumer protection statute;
- c. Is of a continuing nature, and it has produced long-lasting effects; and
- d. Defendants have reason to know their conduct has a significant effect upon Plaintiffs.

121. The nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities.

122. The resources of the communities of the Plaintiffs are insufficient to deal with needs created by the Opioid Crisis, and these limited resources are being unreasonably consumed in efforts to address the Crisis, including efforts to address the overwhelming number of children born with NAS.

123. Defendants' nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer Defendants dissemination of false "scientific" facts and advice.

124. Plaintiff and minor A.K.D. have suffered unique harms different from the public at large, namely, that they personally suffer NAS.

COUNT III – PUBLIC NUISANCE

125. Plaintiffs reassert the allegations of the foregoing paragraphs as if set forth fully herein.

126. The public nuisance is the over-saturation of opioids in West Virginia for non-medical purposes, as well as the adverse social, economic, and human health outcomes associated with widespread illegal opioid use, including the increasing incidence of NAS.

127. All Defendants substantially participated in public nuisance-causing activities.

128. Defendants' public nuisance-causing activities include giving advise relating to selling or facilitating the excessive sale of prescription opioids to the patients and citizens of West Virginia, as well as to unintended users, including newborns and children, people at risk of overdose, and criminals.

129. Defendants' activities unreasonably interfere with the rights of Plaintiffs.

130. The Defendants' interference with these rights of Plaintiffs is unreasonable because it:

- a. Has harmed and will continue to harm the children and public health services of West Virginia;
- b. Is proscribed by statutes and regulation, including the CSA and the consumer protection statute;
- c. Is of a continuing nature, and it has produced long-lasting effects; and
- d. Defendants have reason to know their conduct has a significant effect upon the Plaintiff.

131. The public nuisance undermines public health, quality of life, and safety. It has resulted in high rates of addiction, overdoses, dysfunction, and despair within families and entire communities.

132. The resources of the communities of the Plaintiffs are insufficient to deal with needs created by the Opioid Crisis, and these limited resources are being unreasonably consumed in efforts to address the Crisis, including efforts to address the overwhelming number of children born with NAS.

133. Defendants' public nuisance-causing activities are not outweighed by the utility of Defendants' behavior. In fact, their behavior is illegal and has no social utility whatsoever. There is no legitimately recognized societal interest in failing to identify, halt, and report suspicious opioid transactions. There is no legitimate societal interest in Manufacturer Defendants dissemination of false "scientific" facts and advice.

134. Plaintiff minor A.K.D. also have suffered unique and special harms different from the public at large, namely, that they personally suffer NAS.

COUNT IV - NEGLIGENCE AND GROSS NEGLIGENCE

135. Plaintiffs reassert the allegations of the foregoing paragraphs as if set forth fully herein.

136. Defendants owe a non-delegable duty to Plaintiffs, minor A.K.D. to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

137. There is no social value to Defendants' challenged behavior. In fact, Defendants' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

138. On the other hand, there is immense social value to the interests threatened by Defendants' behavior, namely the health, safety, and welfare of minor A.K.D.

139. Defendants' behavior caused a substantial injury and damage to minor A.K.D.

140. Defendants' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

- a. Assisting the Co-Conspirators in consciously supplying the West Virginia market with highly addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;
- b. Assisting the Co-Conspirators in using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an addiction family history of each and every potential patient;
- c. Assisting the Co-Conspirators in affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;
- d. Assisting the Co-Conspirators in training their employees to encourage prescriptions likely to lead to diversionary market oversupply;
- e. Failing to provide advice to the Co-Conspirators that would encourage effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;
- f. Assisting the Co-Conspirators in creating misleading information with the intention of having prescribing physicians rely upon it.

141. Controlled substances are dangerous commodities. Defendants breached their duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate to the dangers involved in the providing advice, consultation and management service to the Co-Conspirators.

142. Defendants were also negligent or reckless in failing to advise the Co-Conspirators to guard against foreseeable third-party misconduct, *e.g.*, the foreseeable conduct of corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

143. Plaintiffs, minor A.K.D. is without fault, and the injuries to Plaintiffs, minor A.K.D. would not have happened in the ordinary course of events if the Defendants used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

144. The aforementioned conduct of Defendants proximately caused damage to Plaintiff and minor A.K.D.

COUNT V - MEDICAL MONITORING

145. Plaintiffs reassert the allegations in the foregoing paragraphs as if fully set out herein.

146. Plaintiffs assert a claim for Medical Monitoring under the Laws of State of West Virginia seeking reasonable and appropriate costs for future medical monitoring.

147. By definition, plaintiff minor A.K.D. was exposed to opioids, a known toxic substance, at a concentration higher than expected for the general population.

148. Such exposure was proximately caused by the tortious activities of the Defendants.

149. Minor A.K.D. faces a lifetime of latent, dread medical and emotional conditions proven to be linked to in utero exposure opioids including but not limited to brain damage, muscular-skeletal developmental disorders, speech and language disorders, cognitive

developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders and increased risk of addiction.

150. Minor A.K.D. will benefit from medical monitoring for the aforementioned medical and emotional conditions because testing and continued monitoring will bring to light the onset of these medical and emotional conditions so that treatment and intervention may begin at the earliest point possible.

151. Minor A.K.D. will benefit from a medical monitoring program featuring an epidemiological component that collects and analyzes medical monitoring results⁵ so that other heretofore unrecognized latent, dread diseases that may be associated with in utero exposure may be identified so that treating professionals may better care for the Class Members and so that medical professionals engaged in the research and development of new treatment will have access to a broader universe of data.

152. Further, minor A.K.D. will require on-going care for the aforementioned conditions which are known to result from in utero exposure to opioids including but not limited to medical care, psychiatric care, psychological care, physical therapy, cognitive therapy and speech therapy.

153. The harm visited upon minor A.K.D. is irreparable.

154. Given the immense wealth of the Defendants, such injunctive and equitable relief presents no undue burden or irreparable damage to the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Lisa Renee Daniels, on behalf of minor A.K.D. as next friend requests that the Court grant the following relief:

- a. Money damages;
- c. Attorneys' fees and costs;
- d. Pre and Post Judgment Interest;
- d. All such other relief this Court deems just and fair; and
- f. Plaintiffs seek a trial by jury for all counts so triable.

Date: August 20, 2021

Respectfully submitted by:

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